

In the Claims

This listing of claims will replace all prior versions and listings of claims in this application.

1 (original). A stable dried Factor VIII composition containing a stabilizing amount of trehalose in the absence of albumin.

2 (original). The composition, according to claim 1, containing 0.15 to 2.5 mg trehalose per unit of blood factor.

3 (original). The composition, according to claim 1, wherein said Factor VIII is recombinant.

4 (previously presented). The composition, according to claim 1, containing 1.0 to 1.5 mg calcium ion per unit of Factor VIII.

5 (original). The composition, according to claim 1, wherein said composition comprises salt and the molar ratio of said trehalose to said salt is above 1:1.

6 (original). The composition, according to claim 5, containing more than 2.5 moles trehalose per mole of salt.

7 (original). The composition, according to claim 6, containing more than 10 moles trehalose per mole of salt.

8 (original). The composition, according to claim 1, which can be reconstituted with saline to give an isotonic solution.

9 (original). A method of preparing a stable dried blood factor composition containing a stabilizing amount of trehalose in the absence of albumin in which an aqueous solution of Factor VIII containing trehalose is dried at a temperature no greater than 25°C.

10 (original). The method, according to claim 9, in which the solution is dried at a temperature no greater than 10°C.

11 (original). A method for preparing a Factor VIII therapeutic composition for administration to a patient by injection wherein said method comprises reconstituting a stable dried Factor VIII composition containing a stabilizing amount of trehalose in the absence of albumin.

12 (original). The method, according to claim 11, wherein said composition is reconstituted with water.

13 (original). The method, according to claim 11, wherein said composition is reconstituted with saline.

14 (new). A method of preparing a stable dried blood factor composition containing a stabilizing amount of trehalose in the absence of a stabilizing amount of albumin in which an aqueous solution of Factor VIII containing trehalose is freeze-dried in the presence of trehalose and without albumin.

15 (new). A method of preparing a stable dried blood factor composition containing a stabilizing amount of trehalose in the absence of a stabilizing amount of albumin in which an aqueous solution of native Factor VIII containing trehalose is freeze-dried in the presence of trehalose and without albumin.

16 (new). A method of preparing a stable dried blood factor composition containing a stabilizing amount of trehalose in the absence of a stabilizing amount of albumin in which an aqueous solution of recombinant Factor VIII containing trehalose is freeze-dried in the presence of trehalose and without albumin.

17 (new). A method for preparing a composition comprising stable freeze-dried Factor VIII wherein said method comprises freeze-drying Factor VIII with a stabilizing agent consisting essentially of trehalose.

18 (new). A method for preparing a composition comprising stable freeze-dried Factor VIII wherein said method comprises freeze-drying native Factor VIII with a stabilizing agent consisting essentially of trehalose.

19 (new). A method for preparing a composition comprising stable freeze-dried Factor VIII wherein said method comprises freeze-drying recombinant Factor VIII with a stabilizing agent consisting essentially of trehalose.